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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,691	01/18/2002	Steven R. Gullans	18989-016	3785

7590 10/05/2005

MINTZ, LEVIN, COHN, FERRIS,
GLOVSKY and POPEO, P.C.
One Financial Center
Boston, MA 02111

EXAMINER	
KIM, JENNIFER M	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 10/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,691	GULLANS ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 8-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 8-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Upon further consideration, the indicated allowability of claim 5 if rewritten in independent form including all of the limitation of the base claim and any intervening claims indicated on the last Office Action is withdrawn.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, and 8-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for the "inhibiting death of a neuronal cell in a mammal suffering from neurological disorders including Amyotrophic Lateral Sclerosis, Alzheimer's disease, Huntington's disease, Parkinson's disease, diabetic neuropathy, cerebral hypoxia, encephalitis meningitis and stroke". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of inhibiting death of a neuronal cell in a mammal comprising administering to said mammal a composition comprising (17a)-17-hydroxy-19-norpregn-4-en-20-yn-3-one and 17a-(acetyloxy)-6-methylpregna-4,6-diene-3,20-dione compound wherein said composition is administered at a dose sufficient to inhibit oxidative stress-induced neuronal cell death or inhibit apoptotic death of said neuronal cell. The nature of the invention is extremely complex in that it encompasses the actual inhibition of a neuronal cell death in a mammal such that the subject treated with above compounds does not contract neuronal cell death.

Breath of the Claims: The complex of nature of the claims greatly exacerbated by breath of the claims. The claims encompass inhibition of death of a neuronal cell in a mammal of a neurodegeneration disorder and neurological disorders in humans which has potentially many different causes (i.e. many different mutations or combination of mutations, hereditary, infection). Each of which may or may not be addressed by the administration of the claimed compounds.

Guidance of the Specification: The guidance given by the specification as to how one would administered the claimed compounds to a subject in order to actually inhibit death of a neuronal cell comprising mammal suffering from various neurodegenerative disorder and neurological disorders is minimal. All of the guidance provided by the specification is directed towards therapeutic regimen.

Working Examples: There is no working examples regarding actual treatment in vivo data. All of the working examples provided by the specification are directed toward the therapeutic regimen.

State of the Art: While the state of the art is relatively high with regard to treatment of specific neurological disorders (i.e. Alzheimer's disease with single specific compound), the state of the art with regard to inhibiting death of a neuronal cell in a mammal involving various specified neurodegenerative disorder and various neurological disorder is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject to inhibit death of a neuronal cell in a mammal comprising a mammal suffering from various neurodegenerative disorders and neurological disorders.

Predictability of the Art: The lack of significant guidance including vivo data from the specification or prior art with regard to the actual inhibition of death of a neuronal cell in a mammal suffering form the specified neurodegenerative disorder and a specified neurological disorder in a human subject with the

claimed compounds makes practicing the claimed invention unpredictable in terms of actual inhibition of death of a neuronal cell in a mammal suffering from various neurodegenerative disorders and various neurological disorders.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for inhibition of a neuronal cell death in a mammal suffering from the specified neurodegenerative disorder and a specified neurological disorder in a human subject with the claimed compounds . **If unsuccessful**, which is likely given the lack of significant guidance from the specification or prior art regard actual inhibition of a neuronal cell death in a mammal suffering from the specified neurodegenerative disorder and a specified neurological disorder in a human subject with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding inhibition of a neuronal cell death in a mammal suffering from the specified neurodegenerative disorder and a specified neurological disorder in a

human subject with the claimed compounds, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to inhibit a neuronal cell death in a mammal suffering from the specified neurodegenerative disorder and a specified neurological disorder in a human subject with the claimed compounds in the mammal by administration of one of the claimed compounds.

Therefore, a method of inhibiting death of a neuronal cell in a mammal comprising administering to said mammal a composition comprising (17a)-17-hydroxy-19-norpregn-4-en-20-yn-3-one and 17a-(acetyloxy)-6-methylpregna-4,6-diene-3,20-dione compound wherein said composition is administered at a dose sufficient to inhibit oxidative stress-induced neuronal cell death or inhibit apoptotic death of said neuronal cell.

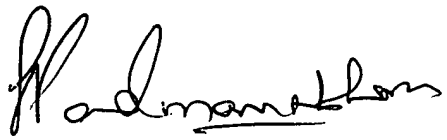
None of the claims are allowed.

Any rejection of record not addressed herein is withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
September 29, 2005